

§ 25.21

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at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34:

(a) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved.

(b) Destruction or other disposition of articles condemned after seizure or whose distribution or use has been enjoined, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(c) Destruction or other disposition of articles following detention or recall at agency request, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(d) Disposition of FDA laboratory waste materials, unless categorically excluded in § 25.30(m).

(e) Intramural and extramural research supported in whole or in part through contracts, other agreements, or grants, unless categorically excluded in § 25.30 (e) or (f).

(f) Establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in §§ 25.30(k) or 25.31 (a), (b), (c), (h), (i), or (j), or 25.32 (a) or (p).

(g) Issuance, amendment, and enforcement of FDA regulations, or an exemption or variance from FDA regulations, unless categorically excluded in § 25.30 (h), (i), or (j), or § 25.32 (e), (g), (n), or (p).

(h) Withdrawal of existing approvals of FDA-approved articles, unless categorically excluded in §§ 25.31 (d) or (k), 25.32(m), or 25.33 (g) or (h).

(i) Approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under § 170.39 of this chapter, and allowing notifications submitted under 21 U.S.C. 348(h) to become effective, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

(j) Establishment of a tolerance for unavoidable poisonous or deleterious substances in food or in packaging materials to be used for food.

(k) Affirmation of a food substance as GRAS for humans or animals, on FDA's initiative or in response to a pe-

tition, under parts 182, 184, 186, or 582 of this chapter and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, unless categorically excluded in § 25.32 (f), (k), or (r).

(l) Approval of NDA's, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, and actions on IND's, unless categorically excluded in § 25.31 (a), (b), (c), (e), or (l).

(m) Approval of NADA's, abbreviated applications, supplements, actions on INAD's, and granting of requests for determination of eligibility for indexing, unless categorically excluded under § 25.33 (a), (c), (d), or (e).

(n) Approval of PMA's for medical devices, notices of completion of PDP's for medical devices, authorizations to commence clinical investigation under an approved PDP, or applications for an IDE, unless categorically excluded in § 25.34.

[62 FR 40592, July 29, 1997, as amended at 65 FR 30355, May 11, 2000; 72 FR 69118, Dec. 6, 2007]

§ 25.21 Extraordinary circumstances.

As required under 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (see 40 CFR 1508.27 for examples of significant impacts). Examples of such extraordinary circumstances include:

(a) Actions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment; and

(b) Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law.